

DEPARTMENT OF PUBLIC HEALTH
DETERMINATION OF NEED GUIDELINES FOR
MAGNETIC RESONANCE IMAGING

August 19, 1997

Determination of Need Program
10 West Street
Boston, MA 02111

I. INTRODUCTION

The purpose of these guidelines is to update the Magnetic Resonance Imaging (MRI) guidelines adopted by the Public Health Council on May 12, 1987, which updated the original December 10, 1985, guidelines. This update reflects the continuing growth in the uses of MRI and the consequent need to have guidelines that reflect this trend. Information on these trends was obtained from the literature, including the Hospital Technology Series published by the American Hospital Association. These revised guidelines will be used to review MRI applications for service expansion in a consistent manner, while fulfilling the Determination of Need mandate to ensure satisfactory access to quality health care at reasonable cost.

MRI technology has continued to improve primarily through software and hardware enhancements. The time required to perform the MRI procedure has been decreased while image quality has improved significantly. New coil design has optimized resolution for small body parts as well as coverage of larger body parts, thereby decreasing overall imaging time. The open design of some new MRI units makes it easier to scan large patients who suffer from claustrophobia. Clinical MRI was used initially for diagnosis in the central nervous system and musculoskeletal system. New developments in both hardware and software and contrast agents have expanded the clinical application of MRI to angiography, imaging of lower and upper extremities, imaging of the thorax, detection and evaluation of breast lesion, functional MRI in neurosurgical planning, and use of MRI in cardiac studies. In view of the clinical indications, interests in the benefits of a noninvasive diagnostic technique as well as emerging new forms of technology and applications, MRI utilization is expected to increase.

II. BACKGROUND

Experience with MRI continues to grow in Massachusetts and elsewhere in the country. The great majority of scans continue to be performed on an outpatient basis, with referrals coming directly from physicians. Various estimates of the probable range of inpatient to outpatient scans, assuming enough MRI capacity existed, range from 20% inpatient to 80% outpatient scans.

In terms of the hardware itself, MRI technology appears to be stable, and obsolescence does not appear to be a barrier to a rapid dissemination of units. Most experts agree that the magnet will not become obsolete and that most improvements will continue to be in the software and surface coils which represent a very small part of the capital costs involved. Magnets currently on the market fall into four broad categories: (1) superconducting high field magnets between 1.0-2.0 tesla; (2) midfield superconducting magnets, 0.35-0.6 tesla; (3) midfield and low field resistive and permanent magnets, 0.2-0.4 tesla; and (4) ultra low field resistive and permanent magnets, 0.04-0.1 tesla. The popularity of high-field MRI units, despite increased costs, is due to more rapid image production, greater patient throughput, and overall superior image quality. Images of quality comparable to higher field systems may be produced by midfield units, but at a cost of longer scan times and at the increased risk of patient motion. Any patient motion during the time of data acquisition degrades the image produced.

The image quality of low field magnets has improved over the years.

Forty-four (44) MRI units have been approved in Massachusetts since September 19, 1995, in the following settings: 14 hospital-based, 19 freestanding, and 11 mobile. Every acute care hospital in Massachusetts has access to MRI services. Many of these hospitals are members of consortia, established to ensure dissemination of this major new technology among academic medical centers as well as community hospitals.

III. FACTORS FOR REVIEW

The following factors, based on the DoN Regulations, will be considered in the review process.

FACTOR ONE: HEALTH PLANNING PROCESS

Standard: Planning for MRI services shall be on a statewide basis and shall consider MRI resources already available in the service area. Applicants shall consult with state planning agencies and any others who can assist in the planning process.

Measure 1: The applicant shall describe planning activities involved with the project, including contacts with state agencies. The description shall include the date of each contact, the nature of each meeting, and the conclusion drawn.

Measure 2: Special consideration will be given to applications with written letters of support for the project from other health care providers, managed care organizations, community health centers, consumer groups and other interested parties in the service area.

Discussion

The sharing of services is an important aspect of health care planning. It not only reduces the unnecessary duplication of services and costs to the health care system, it also allows reasonable patient access to major new technology such as MRI. Thus, applicants are encouraged to discuss potential MRI projects with state planning agencies as well as with other providers, managed care organizations, community health centers, representatives of consumer groups, and other interested parties in the service area.

FACTOR TWO: HEALTH CARE REQUIREMENTS FACTOR

Standard: MRI technology shall be allocated so as to maximize its clinical utility while meeting the health care requirements of the service area.

Measure 1: MRI units will be allocated on a statewide basis to allow more equitable distribution and improved access to MRI services.

Measure 2: Applicants proposing expansion of existing licensed MRI services provided either in a hospital or freestanding facility with fixed or mobile MRI equipment shall demonstrate the following:

- operating
number
- a) the applicant's existing fixed or mobile MRI units have been at 90% of capacity for the past year evidenced by the number of scans performed annually and the hours of operation;
 - b) the applicant as member of a consortium or consortia with mobile service has generated sufficient volume for the past year to support a fixed unit operating at 90% of capacity evidenced by the number of scans performed annually and the hours of operation; and
 - c) documented findings from the Clinical Oversight Committee of the appropriateness and quality of MRI scans and evaluation activities provided in the past three years.

Measure 3: In reviewing comparable applications, special consideration will be given to academic medical centers involved in significant research. Research will be defined as studies conducted to explicit investigational protocols for which patients are not billed.

Discussion

MRI services are currently available and accessible to every citizen of the Commonwealth. However, hospitals and clinics operating at capacity have limited access to physician-operated units, because they can only provide outpatient services. Additionally, academic medical centers conduct MRI research, thereby reducing the capacity available for clinical purposes. It has always been the Department's policy that expansion of existing services is a less costly alternative to development of new services to meet any unforeseen demand. Also, since a large majority of the potential applicants have been providing MRI services for the past decade, use of a need methodology to demonstrate probable utilization of their facility seems no longer necessary. Thus, the guidelines recommend that existing providers be allowed to expand their services provided sufficient demand is present. The potential for inappropriate utilization and quality of care are major concerns of the Department. Documentation of clinical protocols, appropriateness review, quality of MRI scans, and evaluation of the service provides an indication of future use. Accordingly, the Clinical Oversight Committee, a requirement by the existing guidelines in the development of MRI services, is maintained in these guidelines.

FACTOR THREE: OPERATIONAL OBJECTIVES

Standard: MRI Services will be staffed to ensure quality of care and efficient use of resources.

- Measure 1: The MRI service must have a clinical director who is the physician responsible for the clinical operation of the service, including the screening of patients and the taking and interpreting of scans. This physician must have at least six months' documented full-time experience or instruction in MRI, including physics instrumentation and clinical applications.
- Measure 2: All services should be staffed so that screening of requests for MRI scans and/or interpretation of scans will be carried out by physician(s) with appropriate training and familiarity with diagnostic use and interpretation of cross-sectional images of the anatomical region(s) to be examined. At least one of these physicians shall be a board-certified radiologist who is on site a sufficient amount of time to regularly participate in the screening of patients for scans. (This may be the same physician as in (1) above.) These guidelines recognize, however, that physicians with other specialty backgrounds such as cardiology or neurology may have appropriate training in cross-sectional imaging and knowledge of a specific organ system that may make them an integral part of a MRI medical staff.
- Measure 3: A physician must be on site at least 50% of the time when patients are undergoing scans. Scheduling of patients should take this into account, so that patients for which imaging protocols are not routine, or patients whom may need the attention of a physician are scheduled during the times physicians are present. If this physician has less than six months' experience in MRI, his/her work shall be reviewed by the clinical director.
- Measure 4: In freestanding facilities, a person with CPR training shall be present at all times patients are undergoing scans.
- Measure 5: The applicant shall submit the proposed staffing pattern of the unit. Staffing for the unit must consider making provision for meeting the data collection requirement of the Department, as well as providing for adequate technical and patient support during scan times.
- Standard:** **Other support services shall be available to ensure the program's capability to make a diagnosis in the most efficient and effective manner possible.**
- Measure 1: must CT scanning, nuclear medicine, ultrasound and angiography capability be available either on site, through member hospitals in the case of hospitals' consortia, or in the case of other freestanding institutions through signed referral agreements with other area institutions.
- Measure 2: Prior to its operation, each applicant must develop a Clinical Oversight

quality

Committee to review clinical protocols, review appropriateness and of clinical scans, develop educational programs, and supervise data collection and evaluation activities generated by the facility or required by the Department. The Committee shall include, at a minimum:

- a) representatives from at least two specialties other than radiology (e.g., cardiology, neurology, oncology);
- b) physician representative from outside the sponsoring facility, if not represented by (a) above;
- c) in the case of community hospitals, an additional representative from an academic medical center engaged in or knowledgeable about MRI research activities, if not represented by (a) or (b) above; and.
- d) at least two members without equity interests in the facility if not represented by (a) (b) or (c) above.

Measure 3:

Applicants must state their intention to schedule patients based on clinical protocols and must state that ability to pay will not be considered in the acceptance of patients for scans.

Standard:

MRI devices must be proven safe and effective for clinical use.

Measure 1:

Applicants shall identify magnet type and field strength at time of application. Applicants must agree to purchase only those magnets which have pre-market approval from the Food and Drug Administration.

Standard:

All MRI units shall develop and describe training and education plans.

Measure 1:

Applicants must develop and describe plans for education and training of technicians and nurses staffing the unit.

Measure 2:

Applicants are required to offer educational opportunities for area radiologists and other physicians or clinical investigators to become familiar with the general applications of MRI. Applicants must describe such plans.

Discussion:

The operational objectives of a MRI project are that the facility will provide quality MRI services to patients and will facilitate equal access of patients to the service without regard to ability to pay. These guidelines recognize that a number of models of care may meet these

criteria, including both fixed and mobile units, and both hospital-based and freestanding patient care settings.

MRI technology is complicated and continues to require experienced staff to determine the appropriateness of scans, to take adequate scans and to provide accurate interpretations of the data. For these reasons, the qualifications of the medical staff and the development of a clinical oversight committee are major components of quality control under the guidelines. The clinical oversight committee will be of special importance to freestanding centers, which might otherwise not have access to such professional input on a regular basis. These guidelines will form the basis for licensing and periodic inspection by the Division of Health Care Quality for facilities with clinic licenses.

FACTOR FOUR: STANDARDS COMPLIANCE

Standard: **Renovations or new construction associated with MRI projects will meet all relevant construction standards including shielding requirements of the manufacturer.¹**

Measure 1: Schematic drawings shall be submitted for all renovation or new construction associated with the project.

Measure 2: The scope of renovations or new construction shall be presented in the application and discussed.

FACTOR FIVE: REASONABLENESS OF EXPENDITURES AND COSTS

Standard: **MRI services shall be designed to ensure an acceptable quality of service delivery and will be constructed and operated at the lowest reasonable cost.**

Measure 1: The applicant shall discuss in its application how the capital cost estimates presented in the application were derived. The applicant shall discuss the size and type of the MRI unit it expects to purchase, as well as the setting and all related costs.

Measure 2: The applicant shall discuss in its application how the operating cost estimates presented in the application were derived. Applicants shall submit operating cost estimates based on the number of clinical scans projected by the facility.

Measure 3: Applicants shall present any projected cost savings, including substitution for other diagnostic modalities, which may accrue to their institution(s) as a result of the operation of the MRI unit.

Measure 4: The equity contribution shall be a minimum of 20% of the approved maximum capital expenditure.

¹. Revised 7/13/1999 to eliminate requirements by the Department of Public Health in accordance with a memorandum dated 6/25/1999 from Radiation Control Program.

Discussion:

The Department wants to ensure that applicants have researched thoroughly the alternatives for providing the MRI service and that the project proposed represents a reasonable patient expenditure for the service. In determining reasonableness of costs, the Department will use previously approved projects as a guide.

Previously approved MRI facilities in freestanding settings have been in the range of 4,500 to 5,000 gross square feet (GSF), with the larger size facilities associated with housing larger magnets. The average cost per GSF for new construction of facilities of this size has been \$150.00 per GSF (September 1984 dollars), including construction contract, architectural and engineering costs, and site survey and soil investigation. Approved MRI facilities located in hospital settings have ranged from 2,500 GSF to 5,500 GSF, depending on the common space shared by the MRI facility and other existing hospital services. Costs have ranged from \$250.00 to \$306.00 per GSF (September 1984 dollars) for new construction and/or renovation, including construction contract, architectural and engineering costs, and site survey and soil investigation.

A major component of the capital cost has been the purchase of the MRI unit itself. Approved costs for a unit have ranged from \$1.5 million to \$1.7 million (September 1984 dollars), with the larger figure associated with the larger sized magnets.

Staffing of facilities has ranged between 7 to 10 FTEs, with 8 FTEs representing the average. Staffing of facilities must include a clinical director and any additional medical staff required to meet Factor Three, Measures 1, 2, and 3 of the guidelines.

FACTOR SIX: FINANCIAL FEASIBILITY AND CAPABILITY

Standard: **The MRI project shall be within the financial capability of the applicant.**

Measure 1: Applicants shall disclose all sources of revenue applicable to their projects that may be available and shall provide information on the number of projected scans by payer.

Measure 2: Applicants shall specifically make adequate provisions for free care of patients requiring MRI scans, based on probable third-party reimbursement and on area providers' expectations regarding the need

for free care. Applicants shall discuss those provisions in their application.

Discussion:

Schedules A through H of the DoN application and other supportive material should demonstrate that the applicant's financial position is strong enough to take on the proposed project.

FACTOR SEVEN: RELATIVE MERIT

Standard: **The MRI Service as presented in the project proposal shall be superior, on balance, to alternative and substitute means for meeting the unforeseen demand of the target population.**

Measure 1: The applicant shall describe the alternatives considered in the development of this project from the perspective of quality, efficiency and cost or other factors.

Measure 2: The applicant shall demonstrate the ability to provide adequate patient access and a high standard of care to all those within its service areas who require such care, regardless of ability to pay.

Discussion

In evaluating the applications to expand MRI services, the merits of the project will be considered in comparison to other alternatives. Projects must meet the requirements outlined in these guidelines. Special consideration will be given to projects which improve patient access, and provide opportunities for physicians, especially radiologists, to become familiar with MRI and receive training in the taking and interpreting of scans as appropriate. Issues of cost savings may be considered determinant factor(s) by the Department when considering the most appropriate way to increase capacity.

FACTOR EIGHT: ENVIRONMENTAL IMPACT

In most instances, no environmental notification form or report will be required pursuant to 301 CMR 10.32(3) promulgated by the Executive Office of Environmental Affairs pursuant to Massachusetts General Laws Chapter 30, Sections 61-62H.

FACTOR NINE: COMMUNITY HEALTH INITIATIVES

Standard **An amount reasonably related to the cost of the project shall be expended over a five-year period (or other period approved by the Department) for the provision of primary and preventive health care services necessary for underserved populations in the project's service**

area (or other area approved by the Department and reasonably related to the project [(see also 105 CMR 100.551(J)].²

Measure 1: The applicant shall indicate the funding for community initiatives and a plan for the expenditure of such funds for primary and preventive services over a five-year period.

Measure 2: The applicant shall file reports (frequency, content and format to be agreed upon) with the Program Director detailing compliance with its approved plan and, to the extent practicable, an evaluation of the health effects thereof.

Discussion

As part of an on-going effort to improve the health status of the public, the Department has established requirements for DoN applicants to develop and fund primary and preventive health programs as well as diagnostic and therapeutic services in the community. Such programs and services should be aimed at meeting otherwise unmet needs. The Department has published an Informational Bulletin on Community Health Initiatives (most current year available, 1995) which specifies the categories of services and programs that are needed. The applicant is advised to consult with the Department's Office of Healthy Communities and the Community Health Network area(s) (CHNA) in its service area to ensure that the proposed service is consistent with the network's priorities. The proposal should, however, be reasonably related to the type of DoN project for which the applicant is filing. Information on the Bulletin and the contact person in the CHNA may be obtained from the Determination of Need Program.

²Language revised 8/23/99 to be more specific.